

EXHIBIT E

Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure

Overview

The U.S. Department of Health and Human Services (HHS) has a critical responsibility to advance the connectivity of electronic health information and interoperability of health information technology (health IT). This is consistent with its mission to protect the health of all Americans and provide essential human services, especially for those who are least able to help themselves. This work has become particularly urgent with the need to address the national priority of better and more affordable health care, leading to better population health. Achieving this goal will only be possible with a strong, flexible health IT ecosystem that can appropriately support transparency and decision-making, reduce redundancy, inform payment reform, and help to transform care into a model that enhances access and truly addresses health beyond the confines of the health care system. Such an infrastructure will support more efficient and effective systems, scientific advancement, and lead to a continuously improving health system that empowers individuals, customizes treatment, and accelerates cure of disease.

In the past decade, there has been dramatic progress in building the foundation of a health IT infrastructure across the country that is resilient and flexible to accommodate many types of change. Through deliberate policy and programmatic action, the majority of meaningful use¹ eligible hospitals and professionals have adopted and are meaningfully using health IT. This progress has laid a strong base upon which we can build. However, there is much work to do to see that every individual and their care providers can get the health information they need in an electronic format when and how they need it to make care convenient and well-coordinated and allow for improvements in overall health. There is no better time than now to renew our focus on a nationwide, interoperable health IT infrastructure – one in which all individuals, their families, and their health care providers have appropriate access to health information that facilitates informed decision-making, supports

¹ Formally referred to as the Medicare and Medicaid EHR Incentive Programs

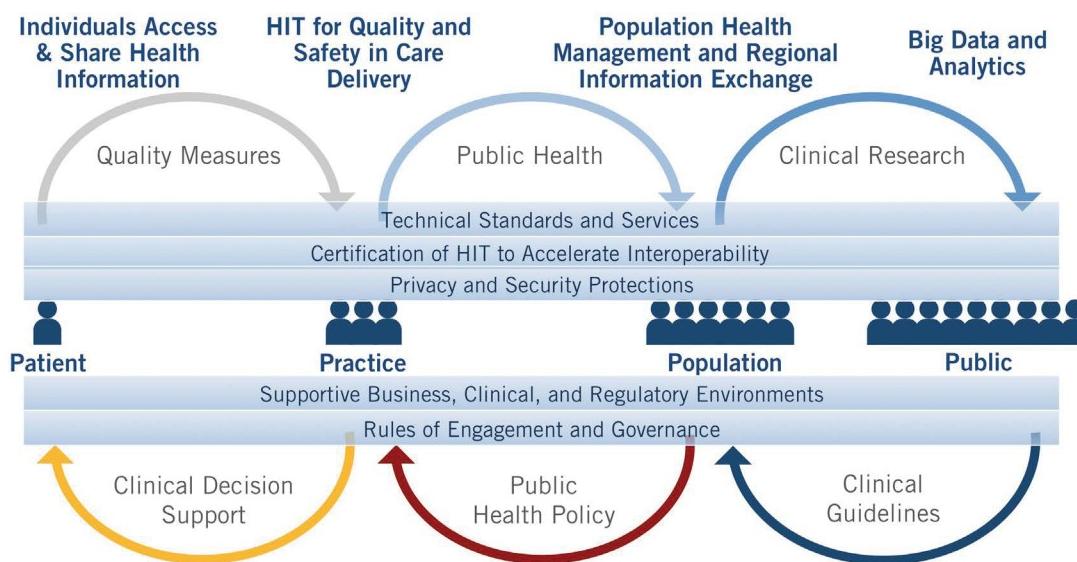


coordinated health management, allows patients to be active partners in their health and care, and improves the overall health of our population. This is not just a technology challenge.

Broad adoption of health IT will require that health information can be easily and appropriately shared to support multiple uses. For instance, the national priority of cost-effective care requires information about quality and use of services to be available to consumers, providers, payers, and employers. Further, physicians expect health IT to enable and support patient care. And finally, there is mounting interest by consumers and innovators in creating meaningful opportunities for individuals to partner in their own health care.

New technology and market changes have opened the door to creating a more integrated and flexible environment that will not only serve us better in the present day, but will allow for ongoing innovation in the future. This paper is an invitation to health IT stakeholders – clinicians, hospitals, public health, technology developers, payers, researchers, policymakers, individuals, and many others – to join ONC in figuring out how we can collectively achieve interoperability across the health IT ecosystem (Figure 1).

Figure 1. Health IT Ecosystem



Vision for the Future

An interoperable health IT ecosystem makes the right data available to the right people at the right time across products and organizations in a way that can be relied upon and meaningfully used by recipients. By 2024, individuals, care providers, communities, and researchers should have an array of interoperable



health IT products and services that allow the health care system to continuously learn and advance the goal of improved health care. This “learning health system” should also enable lower health care costs, improved population health, truly empower consumers, and drive innovation. For example, all individuals, their families, and care providers should be able to send, receive, find, and use health information in a manner that is appropriate, secure, timely, and reliable.²

Individuals should be able to securely share electronic health information with care providers and make use of the information to support their own health and wellness through informed shared decision-making. An interoperable health IT ecosystem should support critical public health functions such as real-time disease surveillance and disaster response, and data aggregation for research and value-based payment that rewards higher *quality* care, not necessarily a higher *quantity* of care.

CONTEXT

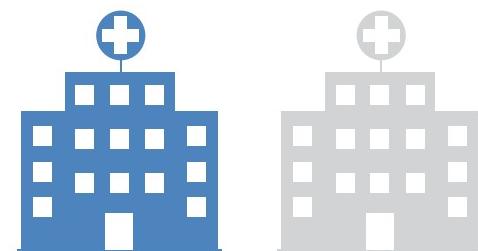
The nation has made dramatic advancements in digitizing the care delivery system during the past decade:

- Over one-half of office-based professionals and more than 8 in 10 hospitals are meaningfully using electronic health records (EHRs), which will require them to electronically exchange standardized patient information to support safe care transitions (Figure 2).³
- One-half of hospitals are able to electronically search for patient information from sources beyond their organization or health system (Figure 3).⁴
- All 50 states have some form of health information exchange services available to support care.⁵

Figure 2.
Hospitals and Professionals That Have Demonstrated Meaningful Use of Certified EHR Technology 2014



Figure 3.
U.S. Hospitals' Capability to Electronically Query Patient Health Information from Outside Their Organization or System 2013



² The term “care providers” is broadly inclusive of the care continuum, reflecting primary care providers, specialists, nurses, pharmacists, physical therapists and other allied care providers, hospitals, mental health and substance abuse services, long-term and post-acute care facilities, home and community-based services, other support service providers, care managers, and other authorized individuals and institutions.

³ http://www.healthit.gov/facas/sites/faca/files/HITPC_Data_Analytics_Update_2014-04-08.pdf

⁴ Office of the National Coordinator for Health Information Technology. ‘U.S. Hospitals’ Capability to Electronically Query Patient Health Information from Outside Their Organization and System,’ Health IT Quick-Stat, no. 25. April 2014

⁵ <http://healthit.gov/policy-researchers-implementers/state-hie-implementation-status>



- Through the Blue Button Initiative, more than half of individual consumers and patients are able to access at least some of their own health information electronically via the combined contributions of providers, health plans, pharmacies, and labs.⁶ Technological innovations such as wearable devices, remote sensing devices, and telehealth support at-home and virtual care models and new roles for patients.

This significant progress has created a growing demand for interoperability that not only supports the care continuum, but supports health generally. Electronic health information needs to be available for appropriate use in solving major challenges such as providing more effective care and informing and accelerating scientific research. Despite significant progress in establishing standards and services to support health information exchange and interoperability, it is not the norm that electronic health information is shared beyond groups of health care providers who subscribe to specific services or organizations. This frequently means that patients' electronic health information is not shared across organizational, vendor and geographic boundaries. Electronic health information is also not sufficiently standardized to allow seamless interoperability, as it is still inconsistently expressed with vocabulary, structure, and format, thereby limiting the potential uses of the information to improve health and care. We must learn from the important lessons and local successes⁷ of previous and current health information exchange infrastructure to improve interoperability in support of nationwide exchange and use of health information across the public and private sector.

Guiding Principles

As we work toward this vision for the future interoperable health IT ecosystem, we will plan and execute our work to align with a set of guiding principles:

- **Build upon the existing health IT infrastructure.** Significant investments have been made in health IT across the care delivery system and in other relevant sectors that need to exchange information with individuals and care providers. To the extent possible, we will encourage stakeholders to build from existing health IT infrastructure, increasing interoperability and functionality as needed.
- **One size does not fit all.** Interoperability requires technical and policy conformance among networks, technical systems and their components. It also requires behavior and culture change on the part of users. We will strive for baseline interoperability across health IT infrastructure,

⁶ See <http://bluebuttonconnector.healthit.gov/> to learn which data holders are offering electronic access to personal health data by consumers.

⁷ See <http://www.healthit.gov/policy-researchers-implementers/hie-bright-spots> for examples of lessons and successes from recent health information exchange efforts.



while allowing innovators and technologists to vary the user experience (the feel and function of tools) in order to best meet the user's needs based on the scenario at hand, technology available, workflow design, personal preferences, and other factors.

- **Empower individuals.** Members of the public are rapidly adopting technology to manage numerous aspects of their lives, including health and wellness. However, many of these tools do not yet integrate information from the health care delivery system. Health information from the care delivery system should be easily accessible to individuals and empower them to become more active partners in their health just as other kinds of data are empowering them in other aspects of their lives.
- **Leverage the market.** Demand for interoperability from health IT users is a powerful driver to advance our vision. As payment and care delivery reform increase demand for interoperability, we will work with and support these efforts.
- **Simplify.** Where possible, simpler solutions should be implemented first, with allowance for more complex methods in the future.
- **Maintain modularity.** Complex systems are more resilient to change when they are divided into independent components that can be connected together. Because medicine and technology will change over time, we must preserve systems' abilities to evolve and take advantage of the best of technology and health care delivery. Modularity creates flexibility that allows innovation and adoption of new, more efficient approaches over time without overhauling entire systems.
- **Consider the current environment and support multiple levels of advancement.** Not every clinical practice will incorporate health information technology into their work in the next 3-10 years, and not every practice will adopt health IT at the same level of sophistication. We must therefore account for a range of capabilities among information sources and information users, including EHR and non-EHR users, as we advance interoperability. Individuals and caregivers have an ongoing need to find, send, receive, and use their own health information both within and outside the care delivery system and interoperable infrastructure should enable this.
- **Focus on value.** We will strive to make sure our interoperability efforts yield the greatest value to individuals and care providers; improved health, health care, and lower costs should be measurable over time and at a minimum, offset the resource investment.
- **Protect privacy and security in all aspects of interoperability.** It is essential to maintain public trust that health information is safe and secure. To better establish and maintain that trust, we will strive to ensure that appropriate, strong, and effective safeguards for health information are in place as interoperability increases across the industry. We will also support greater transparency for individuals regarding the business practices of entities that use their data, particularly those that are not covered by the HIPAA Privacy and Security Rules.



Three-Year Agenda: Send, Receive, Find, and Use Health Information to Improve Health Care Quality

We will develop an interoperability roadmap as articulated in [HHS Principles and Strategy for Accelerating Health Information Exchange](#).

Working with all stakeholders, we will fine-tune and use the health IT infrastructure enabled through implementation of the Health Information Technology for Economic and Clinical Health (HITECH) Act to support transformation of health care to a more patient-centered, less wasteful, and higher quality system. This near-term priority involves improving the interoperability of existing health information networks, and scaling existing approaches for fluidly exchanging health information across vendor platforms to support a broad array of transitions of care and public health. Ensuring that individuals and care providers send, receive, find, and use a basic set of essential health information⁸ across the health care continuum will enhance care coordination and enable health system reform to improve care quality. This means focusing on query-based health information exchange, or the ability to appropriately search for and retrieve health information, in addition to point-to-point information sharing.

Through ONC's standards and certification processes, we will work to further standardize the vocabulary and structure of essential information. We will also address critical issues such as data provenance, data quality and reliability, and patient matching to improve the quality of interoperability, and therefore facilitate an increased quantity of information movement. Working with stakeholders, we will operationalize a common framework to enhance trust by addressing key privacy, security, and business policy and practice challenges to advance secure, authorized health information exchange across existing networks. Finally, we will work with federal and state entities to advance payment, policy, and programmatic levers that encourage use of this information in a manner that supports care delivery reform, improves quality, and lowers costs.

⁸ The basic set of essential health information builds from the common meaningful use (MU) data set incorporated into ONC's health IT certification program as part of the 2014 Edition EHR Certification Criteria and currently used to support three MU objectives included in the Medicare and Medicaid EHR Incentive Programs.

Figure 4: Example three-year agenda use cases:^{*}

Individuals look up their electronic immunization histories when needed.

Primary care providers share a basic set of patient information with specialists during referrals; specialists "close the information loop" by sending updated basic information back to the primary care provider.

Hospitals automatically send an electronic notification and care summary to primary care providers when their patients are discharged.

**These examples are meant as illustrations and are not meant to provide a comprehensive list.*



Six-Year Agenda: Use Information to Improve Health Care Quality and Lower Cost

Over the next six years, the care delivery system will realize enhanced interoperability. Health IT will continue to enable individuals to be active participants in managing their care as an important contributor of information to the health record (e.g., patient experience, self-rated health, and self-generated data). Individuals, care providers, and public health departments will send, receive, find and use an expanded set of health information across the care continuum to support team-based care. Care providers, such as those in schools, ambulances, and prisons will be able to appropriately exchange and use relevant health information. Remote monitoring will be enabled through better interoperability between medical devices, home-monitoring tools, and health information technology, including EHRs. Multi-payer claims databases, clinical data registries, and other data aggregators will incrementally become more integrated as part of an interoperable technology ecosystem.

Health care providers will also be able to aggregate and trend information within and across groups of patients based on information from multiple data sources to monitor health disparities and quality improvement opportunities (population health management). As value-based payment gains traction across Medicare, Medicaid, and commercial payers and purchasers, there will be new methods of measuring clinical quality that represent the most important aspects of care delivery and health outcomes. We will work with stakeholders to refine standards, policies, and services to automate the continuous quality improvement process and deliver targeted clinical decision support that fits into a clinician's workflow to close care gaps and improve the quality and efficiency of care.

Figure 5: Example six-year agenda use cases:^{*}

Individuals regularly contribute information to their electronic health records for use by members of their care team.

Individuals integrate data from their health records into apps and tools that enable them to better set and meet their own health goals.

Primary care providers and authorized researchers are able to understand how well controlled diabetic patient population's glucose levels (i.e., A1C values) are and how often those patients have been hospitalized based on standardized information from multiple sources.

Clinical settings and public health are connected through bi-directional interfaces that enable seamless reporting to public health departments and seamless feedback and decision support from public health to clinical providers.

^{*}These examples are meant as illustrations and are not meant to provide a comprehensive list.



10-Year Agenda: The Learning Health System

By year 10, the nation's health IT infrastructure will support better health for all through a more connected health care system and active individual health management. Information sharing will be improved at all levels of public health, and research will better generate evidence that is delivered to the point of care. Advanced, more functional technical tools will enable innovation and broader uses of health information to further support health research and public health.

The evolution of standards, policies, and data infrastructure over the next 10 years will enable more standardized data collection, sharing, and aggregation for patient-centered outcomes research. Continuous learning and improvement will be feasible through analysis of aggregated data from a variety of sources. Health IT systems will enable both analysis of aggregated data and use of local data at the point of care through targeted clinical decision support (CDS). CDS will improve care by taking into account information such as an individual's genetic profile, local trends in disease prevalence, antibiotic resistance, occupational hazards, and other factors.

The process of clinical trial recruitment, data collection, and analysis will be accelerated and automated. Retrospective analyses will allow for rapid inquiry around many aspects of public health, health care quality, outcomes, and efficiency. Public health surveillance will be dramatically improved through better outbreak detection and disease incidence and prevalence monitoring. Interoperable health IT will also help contain outbreaks and manage public health threats and disasters.

The nation's health IT infrastructure will facilitate health improvement through active individual health management, improved information sharing with public health, and the ability for research to generate evidence that is delivered to the point of care.

Figure 6: Example 10-year agenda use cases:*

Individuals manage information from their own electronic devices and share that information seamlessly across multiple electronic platforms as appropriate (health care providers, social service providers, consumer-facing apps and tools, etc).

Primary care providers can select effective medications for patients with certain conditions based on their genetic profiles and results of comparative effectiveness research.

Individuals, care providers, public health and researchers contribute information and learn from information shared across the health IT ecosystem, with rapid advancement in methods for deriving meaning from data without sharing PHI.

**These examples are meant as illustrations and are not meant to provide a comprehensive list.*



How will we get there?

It will take a strategic and focused effort by the federal government, in collaboration with state, tribal, and local governments and the private sector. We will aim to develop a shared agenda that focuses on five critical building blocks for a nationwide interoperable health information infrastructure:

1. Core technical standards and functions
2. Certification to support adoption and optimization of health IT products and services
3. Privacy and security protections for health information
4. Supportive business, clinical, cultural, and regulatory environments
5. Rules of engagement and governance

These building blocks are interdependent and progress must be incremental across all of them over the next decade to realize this vision. We will develop a more comprehensive set of use cases and goals for three, six and ten-year timeframes that will guide work in each of the building blocks, including alignment and coordination of prioritized federal, state, tribal, local, and private sector actions.

BUILDING BLOCK #1: CORE TECHNICAL STANDARDS AND FUNCTIONS

Through our Standards & Interoperability (S&I) Framework, ONC will continue to work with industry stakeholders and federal and state governments to advance core technical standards for terminology and vocabulary, content and format, transport, and security. These standards will enable, at a minimum, the following essential services for interoperability:

1. Methods to accurately match individuals, providers and their information across data sources
2. Directories of the technical and human readable end points for data sources so they and the respective data are discoverable
3. Methods for authorizing users to access data from the data sources
4. Methods for authenticating users when they want to access data from data sources
5. Methods for securing the data when it is stored or maintained in the data sources and in transit, i.e., when it moves between source and user
6. Methods for representing data at a granular level to enable reuse
7. Methods for handling information from varied information sources in both structured and unstructured formats

ONC will also work toward flexible and dynamic technical tools to support interoperability for primary and secondary use of health information, such as the architecture described in the JASON report prepared for the Agency for Healthcare Research and Quality, [A Robust Health Data Infrastructure](#).



BUILDING BLOCK #2: CERTIFICATION TO SUPPORT ADOPTION AND OPTIMIZATION OF HEALTH IT PRODUCTS AND SERVICES

ONC will leverage the ONC Health IT Certification Program to ensure that a broad spectrum of health IT conforms to the technical standards necessary for capturing and exchanging data to support care delivery. Certification will be used to test that health IT conforms to standards, and also to certify that the technology has the ability to interoperate with other data sources so that users can exchange and use information from other systems. To increase flexibility in our regulatory structure, ONC has proposed that content and transport functions of technology be tested for certification separately. ONC has also been responsive to a demand for expansion of the certification program's scope to include health IT used in a broader set of health care settings, such as long-term and post-acute care and behavioral health. Ensuring consistent adoption of standards and policies for health IT applications used across all settings of care will support interoperability and health information exchange.

BUILDING BLOCK #3: PRIVACY AND SECURITY PROTECTIONS FOR HEALTH INFORMATION

ONC will strive to ensure that privacy and security-related policies, practices, and technology keep pace with the expanded electronic exchange of information for health system reform. We will continue to assess evolving models of health information exchange to identify and, with stakeholder input, develop solutions to address weaknesses and gaps in privacy protections. We will encourage the development and use of policy and technology and workflow practices to advance patients' rights to access, amend, and make informed choices about the disclosure of their electronic health information. We recognize that there are certain state and federal laws under which some patients must give affirmative consent to the disclosure of their health information (often related to a "sensitive" health condition such as behavioral health or genetic information), a privacy protection that is more stringent than the HIPAA Privacy Rule. ONC will endeavor to ensure that these patients will not be left on the wrong side of the digital divide. We will work to improve standards, technology, and workflow that enable the electronic collection and management of consent as well as the electronic exchange of related information within existing legal requirements (including notice of redisclosure restrictions). We will also invest in methods and approaches that support distributed analytics and open evidence sharing without sharing PHI. Continued coordination across federal and state governments is needed to develop, implement, and evolve appropriate privacy and security policies for various types of health information exchange.

Expanding interoperability and exchange may also pose new security challenges. We will work with the National Institute of Standards and Technology (NIST) and other stakeholders to expand the options for ensuring, at an appropriate level of certainty, that those who access health information electronically are who they represent themselves to be. We will continue to assess and improve policies and standards that help ensure health information is only accessed by authorized people



and is used in reasonable and transparent ways. We will also work with the private sector to address emerging cyber threats.

Given our support for electronic access by individuals to their own health information, we will also be mindful of the privacy and security risks created when information exits the realm of HIPAA covered entities. We will support developers creating health tools for consumers to encourage responsible privacy and security practices and greater transparency about how they use personal health information. In addition, we will collaborate with the Office for Civil Rights and other agencies to encourage greater consumer education about the benefits of health information exchange and the steps they can take to safeguard their own data.

As we expand health information exchange, it is important that all stakeholders (the government, health care providers and plans, vendors, developers, patients and their caregivers) recognize their responsibility in protecting health information. We intend to continue our outreach and technical assistance to help everyone reach this goal.

BUILDING BLOCK #4: SUPPORTIVE BUSINESS, CLINICAL, CULTURAL, AND REGULATORY ENVIRONMENT

While the Medicare and Medicaid EHR Incentive Programs have been a primary motivator for the adoption and use of certified EHR technology, these programs alone are insufficient to overcome barriers to our vision of information sharing and interoperability as outlined above. Current policies and financial incentives often prevent such exchange, even when it is technically feasible. To ensure that individuals and care providers send, receive, find, and use a basic set of essential health information across the care continuum over the next three years, we need to migrate policy and funding levers to create the business and clinical imperative for interoperability and electronic health information exchange.

In collaboration with employers, federal agencies, and private payers, ONC will help define the role of health IT in new payment models that will remove the current disincentives to information exchange. Incremental steps to accelerate health information exchange will initially stem from Affordable Care Act (ACA) delivery reform programs and Medicare payment regulations. HHS will consider ways in which the adoption and use of ONC-certified health IT products can be aligned with and encouraged by Medicare and Medicaid payment policy, and other HHS programs funding health care delivery so that care delivery transformation and interoperability evolve in tandem.

With regard to individual access to health information and the engagement it enables, a significant barrier is a lack of knowledge among members of the public that access to health information is becoming increasingly available, and a cultural bias against taking advantage of it. Many patients are intimidated or embarrassed to ask for copies of their records or to ask health-related questions of their providers. To address these cultural barriers, we will encourage providers to proactively offer



access to health information for their own patients, and using consistent marketing and messaging via the Blue Button Initiative, encourage diverse stakeholders including data holders and consumer advocacy organizations to educate individuals about their rights and the benefits of access to and use of health information.

We will also work with states, employers, consumers, providers, technology developers, payers, and others to support efforts driving appropriate health information exchange for improvements in care and to see that any regulatory and business barriers preventing data flow are reduced and/or removed.

BUILDING BLOCK #5: RULES OF ENGAGEMENT AND GOVERNANCE OF HEALTH INFORMATION EXCHANGE

The HITECH Act charged ONC with establishing a governance mechanism for the nationwide health information network.

We view the nationwide health information network as a continually expanding ecosystem of electronic exchange activities and network service providers across the nation that rely on a set of standards, policies, and services to meet electronic exchange needs including the privacy, security, and appropriate use of the information exchanged.

This market includes many forms of electronic exchange and network service providers, ranging from simple forms (such as direct electronic exchange of health information between two known providers) to more sophisticated forms (such as query and response techniques). Governance will facilitate trust and interoperability across all the diverse entities and networks that provide exchange services so that health information follows individuals regardless of where and when they access care.

Looking forward

In 2014, ONC will build on our existing governance framework and principles to ensure individual access, privacy, transparency, responsible financial and business practices, and use of federal standards to support health information exchange. As needed, ONC will identify the “rules of the road” necessary for information to flow efficiently across networks and will transition to a governance approach for health information exchange that will likely involve both policy and collaboration across industry, government, and consumer representatives.

Experience has demonstrated that while trust can be established among specific, known groups of health information trading partners (providers, public health departments, payers, etc.) through local governance, data use agreements, and other contractual arrangements (constituting a trust community), scaling trust across communities requires assurance that each adheres to a minimum set of common security and business practices. Our governance approach must consider



a common framework for privacy, security, technology, data, and business practices, provide assurance to trust communities that each abides by that framework (including a process for dispute resolution and reconciliation), and maintain minimum technical tools where needed to make scaling trust easy.

We will seek input and collaboration with federal agencies to inform governance implementation and ensure broad participation across existing operating health information networks, including those focused at the vendor, enterprise, regional, and state levels. We seek to promote competition among network service providers in a way that avoids providers or individuals being "locked in" to one mechanism to exchange health information, limiting their ability to share health information and coordinate care efficiently.

It will take time to build a fully interoperable infrastructure of coordinated care and communication across health care providers, patients, and public health entities that improves health care quality, lowers health care costs, and improves population health. HHS is fully committed to ensuring ubiquitous, standards-based interoperability of health information across all care settings through a multi-year approach that is consistent, incremental, yet comprehensive. No one person, organization, or government agency alone can realize this vision of an interconnected health system. But together, we can achieve the promise and potential of health information technology to improve the health of all.